

December 1, 1999

Document Management Branch
HFA-305
Food & Drug Adm.
5630 Fisher's Lane, Rm 1061
Rockville, Maryland 20852

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RE: Docket #97N-484S

Dear Sir:

It has come to my attention that the FDA has proposed another regulation regarding the use of allograft tissues, including ligaments and bone in it's various forms. Standard clinical practice for better than thirty years has involved the use of bone banks and I think it would be grossly inappropriate to start regulating it, other than for quality assurance of the material itself. A change in this practice inevitably would "screw up" the ability to treat our patients. Some small gain for such tremendous cost and confusion is not worth it.

Similarly, allograft tissues have been used extensively in orthopaedics for better than fifteen years in a variety of forms and this has included ligaments as well as menisci and long bones for tumor reconstructions. This again has been standard clinical practice for some time, all which have passed clinical parameters with rigorous test design. Like bone, the materials themselves have undergone vigorous testing for infection and for sterilization of a variety of pathogens, etc. T

he FDA must make some effort to understand the clinical practice of musculoskeletal medicine. I have been involved in the Genzyme Carticele project at length and it is clear that there is a major lack of understanding in how musculoskeletal medicine works, it's scientific literature and day to day practice. This would create havoc in our field. Please make some effort to understand the practice of this area of medicine and surgery before making a regulation which will screw it up so badly.

Sincerely,

Frank A. Burke, M.D.
President
Bluegrass Orthopaedics
120 N. Eagle Creek Dr.
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FB/ Frank A. Burke, M.D./EC:dfg

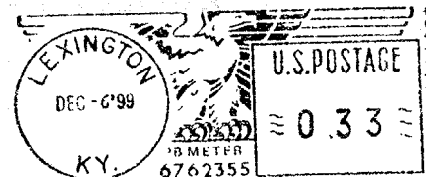
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